

NORTHWEST ALLERGY CLINIC, INC.

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September 6, 2005

FDA Docket
2005N/0279
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sirs:

In requesting the information about how to define gluten-free foods products, the FDA apparently has sent out a request for input. I am a celiac patient and am very sensitive to gluten. The problem with gluten, you are well aware of, if you have reviewed the recent position paper on celiac disease by the National Institute of Health. The definition of gluten-free, based on your original question, is what should gluten-free mean on a food label and why. This certainly would mean that that product should be totally and absolutely free of any gluten content whatsoever. Obviously, gluten most likely comes from wheat, rye, barley and oats. The celiac patient will become very ill if he obtains even a small amount of gluten. This is the reason for the individual to know absolutely if the product says gluten-free and that it is totally, without a doubt, free of any substances that might be related. There are a number of substances that have contamination in shipping and other areas that get gluten in small amounts but it is still significant enough to make the patient sick.

The next question that you have is how do you identify foods that do not contain gluten. Of course, one has to rely on the food manufacturer, who produces the food products. This provides a time consuming problem for this type of individual as one must constantly be calling the providers of food products and asking if they are gluten free. Many times, this has to be done quite frequently as at time one will receive one type of answer and then another time another type. Many times the patient may actually risk the food to find out whether it will make one ill or not. This amount of time could be saved if the foods were identified as free of gluten.

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Re: FDA Docket

Page 2

As you are aware, celiac disease is increasing remarkably in this country based on the ability to diagnose it much easier. Therefore we are now seeing the ratios dropping in the range of 1 to 100 people instead of the old 1 to 10,000 estimate for this area. I certainly feel that in the future we will have to have national testing before school age, as many countries in the European area do. This is a chronic debilitating disease. I spent many years with severe complaints, seeing multiple doctors until I was finally diagnosed at the Mayo Clinic at the age of 72. I have since tested my family and also genetic testing to see about their problems. There are many, many times that I wish how this diagnosis could have come earlier in my life and how I could have spent all of the time that I was ill in doing work as a physician and helping other people rather than trying to seek a cause for my illness. The ability to find foods also allows gluten sensitive patients to be able to travel, to attend meetings and seminars and other special interests without having to constantly worry about having a supply of food available that they can eat.

What percentage of foods, in which types purchased are marked gluten-free? Certainly at the present time is limited. The whole purpose of the Consumer Protection Act, as I understand it about the labeling, is to allow people who have not only gluten sensitivity but other contaminants in nuts and other food allergens to identify to people so that they will not have serious anaphalytic reactions. The celiac does not have a serious anaphalytic-type reaction usually but it also can develop many other diseases along with a hidden-type celiac disease which will relate in many cases to as many as a hundred diseases. So the importance is the foods that are marked gluten-free allows a person to live a more normal life and to be better nutritionally provided for and to be able to be more productive. It also has a chance to help eliminate a large number of other diseases that are growing in our population.

The fourth question, does gluten-free printed on a product label influence your decision to purchase products having the same ingredients? This really does not influence you to buy products having the same ingredients because one cannot be sure if the ingredient on the label is of the same quality as the products that are labeled gluten-free. Therefore, one cannot buy a food that is labeled gluten-free from one company and then turn around and buy that same food from another company and feel that he/she is not going to be ill. It is critically important that the gluten-free label on foods be applied to all significant foods, across the board, so that the person is able to find adequate food and nutrition and be able to survive and be a productive citizen.

I hope that these comments will be of some value to the FDA and I hope that the FDA will decide to make specific labeling, even though it may cost the company a little bit of money, it will certainly in the long run increase their sales as we have more and more people who develop celiac disease and other gluten problems in the United States.

Sincerely yours,


John L. Davis, M.D.

JLD/cl



Celiac Sprue Association®

Celiacs Helping Celiacs

Take Action NOW-

FDA requests your comments NOW before regulations are written.

The Food Allergen Labeling and Consumer Protection Act requires
the **FDA to DEFINE GLUTEN-FREE** for food labels.
For FDA to define "gluten-free" they need your input to the questions below.

Your letter or e-mail must address these items to be useful to Federal Drug Administration.
Details in Federal Register Vol 70 No.137 Tuesday, July 19, 2005 Information, links and e-mail submission at www.csaceliacs.org

- 1) What should "gluten-free" mean on a food label? Why? —
- 2) How do you identify foods that do not contain gluten? Time spent identifying foods? —
- 3) What percentage of foods and which types purchased are marked "gluten-free"? —
- 4) Does "gluten-free" printed on a product label influence your decision to purchase products having the same ingredients? To what extent?

ONLY Comments sent to FDA Docket # 2005N-0279 become public record!

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DEADLINE FOR
YOUR COMMENTS
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